

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: SB 1160

INTRODUCER: Senator Haridopolos

SUBJECT: Immunizations

DATE: February 14, 2006

REVISED: 02/15/06

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------------|----------------|-----------|------------------------|
| 1. | <u>Garner</u> | <u>Wilson</u> | <u>HE</u> | <u>Fav/1 amendment</u> |
| 2. | <u></u> | <u></u> | <u>ED</u> | <u></u> |
| 3. | <u></u> | <u></u> | <u>HA</u> | <u></u> |
| 4. | <u></u> | <u></u> | <u></u> | <u></u> |
| 5. | <u></u> | <u></u> | <u></u> | <u></u> |
| 6. | <u></u> | <u></u> | <u></u> | <u></u> |

Please see last section for Summary of Amendments

- Technical amendments were recommended
- Amendments were recommended
- Significant amendments were recommended

I. Summary:

This bill requires each licensed assisted living facility, which has 11 or more licensed beds to implement a program to offer immunizations against influenza viruses and pneumococcal bacteria to all residents age 65 or older. The bill also requires the Department of Health (DOH) to annually send to each assisted living facility a reminder notice of this requirement.

The bill requires district school boards and private school governing authorities to provide every student's parent specified information about meningococcal disease in accordance with the recommendations of DOH. The bill requires DOH to adopt rules specifying the age or grade level of students to receive the information consistent with recommendations of the Centers for Disease Control and Prevention (CDC). It requires DOH to make information about the disease available to district school boards and private school governing authorities, who shall determine the means and methods for providing this information to students' parent.

This bill amends ss. 381.005 and 1003.22, F.S.

II. Present Situation:

Influenza

Influenza, commonly called the “flu,” is caused by the influenza virus that infects the respiratory tract. Flu is a major cause of illness and death in the United States. Between 5 percent and 20 percent of the of the U.S. population gets the flu on an annual basis; more than 200,000 people are hospitalized from flu complications; and about 36,000 people die from flu each year, according to CDC.¹ The virus is typically spread from person to person; when an infected person coughs or sneezes, the virus is expelled into the air. Influenza can cause severe illness and lead to serious and life-threatening complications in all age groups. Complications such as bacterial pneumonia, dehydration, and worsening of underlying chronic conditions (such as congestive heart disease and asthma) occur most often in persons who are particularly vulnerable, such as elderly persons and persons with chronic conditions.²

Vaccines are effective in protecting individuals against illness or serious complications of flu, particularly those who are at high risk for developing serious complications from the disease. The Advisory Committee on Immunization Practices of CDC (ACIP) recommends that, when vaccine is available, persons in high-risk groups including individuals aged 65 or older, and people with chronic diseases of the heart, lung, or kidneys, diabetes, immunosuppression, or severe forms of anemia, should be vaccinated against the flu. The ACIP also recommends that residents of nursing homes and other chronic-care facilities, children receiving long-term aspirin therapy, and any person who is in close or frequent contact with anyone in the high-risk group, such as health care personnel and volunteers, be vaccinated.³ The CDC recommends that the optimal time to be vaccinated against flu is in the fall.⁴

Medicare coverage for flu shots for the elderly began in 1993. Flu shots are available at no cost to individuals enrolled in Medicare Part B from physicians or providers who bill Medicare. If patients receive their flu vaccines from physicians or providers who do not bill Medicare, the physician can be reimbursed by the beneficiary at a specified rate. For September 1, 2005, through August 31, 2006, the influenza vaccine reimbursement rate is \$12.06.⁵ The Medicaid program covers costs for flu vaccine and administration for Medicaid patients who are residents of nursing homes and long-term care facilities who are not the recipients of Medicare benefits.

¹ *Influenza: The Disease*, November 15, 2004, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/flu/about/disease.htm>.

² See Fact Sheet *Influenza (Flu) Key Facts about the Flu*, November 10, 2004, Department of Health and Human Services Centers for Disease Control and Prevention; *Flu*, January 2005, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, available at <http://www.niaid.nih.gov/factsheets/flu.htm>.

³ Because of the influenza vaccine shortage during the 2004-05 flu season, the CDC twice revised its recommendations regarding who should receive the vaccine. Persons age 65 and older and residents of nursing homes and long-term care facilities were always in the highest priority groups. See fn.2, *Recommended Adult Immunization Schedule United States October 2004-September 2005, Summary of Recommendation Published by the Advisory Committee on Immunization Practices*, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.immunization.org/downloads/adult-schedule.pdf>.

⁴ *Fact Sheet Influenza (Flu) Key Facts about the Flu Vaccine*, January 27, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/flu/protect/pdf/vaccinekeyfacts.pdf>.

⁵ http://new.cms.hhs.gov/AdultImmunizations/02_Providerresources.asp#TopOfPage

Pneumococcal Disease

Pneumococcal pneumonia is a lower respiratory tract infection caused by the bacterium *Streptococcus pneumoniae* which colonizes in the lungs, but can potentially invade the bloodstream (causing bacteremia) and the tissues and fluids surrounding the brain and spinal cord (resulting in a form of meningitis, an inflammation of the tissues and fluids surrounding the brain and spinal cord).⁶ “Pneumonia” is not a single disease. It can have over 30 different causes. The five main causes of pneumonia in the U.S. are bacteria, viruses, mycoplasmas, chemical exposure, and exposure to other infectious agents such as fungi (including pneumocystis).⁷

Pneumococcal pneumonia is the most common cause of bacterial pneumonia acquired outside of hospitals.⁸ The CDC estimates indicate that *S. pneumoniae* causes 500,000 cases of pneumonia and is blamed for 40,000 deaths annually in the United States.⁹ This mortality figure is the highest among vaccine-preventable bacterial diseases in the U.S.¹⁰

Medicare pays for one pneumococcal vaccination for all beneficiaries. One vaccination at age 65 generally provides coverage for a lifetime, but for some high-risk persons, a booster vaccine is needed. Medicare will also pay for the booster vaccination for high-risk persons if 5 years have passed since their last vaccination. No coinsurance or co-payment applies to this benefit, and an individual does not have to meet his or her deductible to receive the benefit. Medicare pays separate rates for the administration and cost of the pneumococcal vaccine. For September 1, 2005, through August 31, 2006, the pneumococcal vaccine reimbursement rate is \$24.57.¹¹

Immunization Requirements in Nursing Homes and Assisted Living Facilities

Assisted living facilities are licensed under part III of ch. 400, F.S.¹² Currently, there is no requirement that assisted living facilities offer immunizations against the influenza virus to their residents either in ch. 400, F.S., or in DOH’s primary and preventive health services statutes (s. 381.005, F.S.). Nursing homes licensed under part II of ch. 400, F.S., are required to immunize residents against influenza viruses. Section 400.141(22), F.S., specifies when the immunizations must be given, requires consent by the resident being immunized, and provides an exemption for medical contraindications and religious or personal beliefs.

An immunization requirement similar to the one proposed in SB 1160 is found in s. 400.121(23), F.S., and directs licensed nursing facilities to assess their residents for pneumococcal

⁶ *Facts About Pneumococcal Disease for Adults*, July 2002, National Coalition for Adult Immunization, available at <http://www.nfid.org/factsheets/pneuadult.html>.

⁷ *Pneumonia*, October 2002, American Lung Association, available at <http://www.lungusa.org/site/pp.asp?c=dvLUK900E&b=356921>.

⁸ *Pneumonia Fact Sheet*, June 2005, American Lung Association, available at <http://www.lungusa.org/site/pp.asp?c=dvLUK900E&b=35692>.

⁹ *Pneumococcal Pneumonia*, updated December 13, 2004, Department of Health and Human Services National Institute of Allergy and Infectious Diseases, available at <http://www.niaid.nih.gov/factsheets/pneumonia.htm>.

¹⁰ *Morbidity and Mortality Weekly Report, Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices*, April 4, 1997, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>.

¹¹ http://new.cms.hhs.gov/AdultImmunizations/02_Providerresources.asp#TopOfPage

¹² The Assisted Living Facilities Act, ss. 400.401 – 400.454, F.S.

polysaccharide vaccine (PPV) immunization eligibility within 5 days of admission, and vaccinate those eligible residents with the PPV vaccine within 60 days, in accordance with CDC recommendations. Moreover, that section also indicates that residents may elect to receive PPV immunization from a personal physician if proper documentation is submitted. However, unlike the requirement for provision of influenza vaccination in s. 400.121(22), F.S., this section does not make reference to obtaining a resident's consent prior to PPV immunization. Despite this, both sections note that the immunizations required are "subject to exemptions for medical contraindications and religious or personal beliefs."

Meningococcal Disease and Immunization

The meningococcal bacterium can cause a life-threatening infection of the bloodstream, meningitis (infection of the brain and spinal cord coverings), or both. Sometimes referred to as spinal meningitis, bacterial meningitis can be quite severe and may result in brain damage, hearing loss, or learning disability. Death occurs in 10 to 15 percent of the 2,600 cases of meningococcal meningitis that are reported in the U.S. each year. The largest incidence of the disease is in children under age five, with a second peak in children and young adults between the ages of 15 and 24.¹³

Before the 1990s, *Haemophilus influenzae* type b (Hib) was the leading cause of bacterial meningitis, but new vaccines being given to all children as part of their routine immunizations have reduced the occurrence of invasive disease due to *H. influenzae*.¹⁴

There are five subtypes (or Serogroups) of the bacterium that cause meningococcal meningitis (Serogroups A, B, C, Y, and W-135). Two vaccines are available to immunize against Serogroups A, C, Y and W-135: Menomune, licensed in 1981, and Menactra (also known as MCV-4), licensed in 2005.¹⁵

On May 26, 2005, the CDC recommended routine administration of the Menactra vaccine for all children 11-12 years old. The CDC had previously recommended the vaccination of unvaccinated adolescents at high school entry, and college freshmen living in dormitories "to help achieve vaccination among those at highest risk for meningococcal disease. As the vaccine supply increases, CDC hopes, within three years, to recommend routine vaccination for all adolescents beginning at 11 years of age."¹⁶

In September 2005, CDC and the U.S. Food and Drug Administration (FDA) issued an alert¹⁷ after reports made to the Vaccine Adverse Event Reporting System (VAERS) indicated that five

¹³ *Vaccine Information Meningococcal Disease*, updated March 11, 2005, National Network for Immunization Information, available at http://www.immunizationinfo.org/vaccineInfo/vaccine_detail.cfv?id=15.

¹⁴ *Division of Bacterial and Mycotic Disease, Disease Information, Meningococcal Disease*, Department of Health and Human Services Centers for Disease Control and Prevention, available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm.

¹⁵ There is no licensed vaccine for Serogroup B in the U.S. *Vaccine Information Meningococcal Disease*.

¹⁶ *Press Release: CDC Recommends Meningococcal Vaccine for Adolescents and College Freshman*, May 26, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/od/oc/media/pressrel/r050526b.htm>.

¹⁷ *FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain Barre Syndrome*, September 30, 2005, U.S. Food and Drug Administration, available at <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01238.html>.

adolescents had developed Guillain-Barre Syndrome (GBS)¹⁸ following administration of the Menactra vaccine. By November 2005, six Menactra recipients (all ages 17 or 18) experienced an onset of GBS 14-31 days after vaccination.¹⁹ Although the timing of the onset of neurological symptoms (within the first month of vaccination) was alarming, it was not immediately known if there was a sound causal relationship between Menactra vaccination and GBS, as the six reported cases of GBS among approximately 2.5 million doses of Menactra distributed nationally is a rate similar to what might have been expected to occur by chance alone.²⁰

The CDC and the American Academy of Pediatrics both continue to recommend Menactra administration for all 11 and 12 year olds at the pre-adolescent visit.

Florida's Public School Vaccination Schedule

In Florida, the following immunizations are required by age and school grade.²¹

Immunizations required for preschool entry (age-appropriate doses as are medically indicated):

- Diphtheria-Tetanus-Pertussis Series
- Haemophilus influenzae type b (Hib)
- Hepatitis B
- Measles-Mumps-Rubella (MMR)
- Polio Series
- Varicella

Immunizations required for kindergarten entry:

- Diphtheria-Tetanus-Pertussis Series
- Hepatitis B Series
- Measles-Mumps-Rubella (two doses of Measles vaccine, preferably as MMR)
- Polio Series
- Varicella

¹⁸ According to the American Academy of Pediatrics and the National Institute of Neurological Disorders and Stroke, Guillain-Barre Syndrome (GBS) is a severe neurological disorder causing weakness of the body's extremities as a result of an inflammatory demyelination of peripheral nerves. This weakness can intensify rapidly, rendering certain muscles useless and, when severe, leave a patient almost totally paralyzed. Although anyone can be affected by GBS – the disease can occur at any age and both sexes are equally susceptible to onset – the incidence rate is only about one person in 100,000. Presently, there are no known cures for GBS, although several therapies (including plasma exchange and high-dose immunoglobulin therapy) are utilized to accelerate recovery. Recovery periods for patients experiencing GBS are varied and can range from a few weeks to a few years, although roughly 30 percent of patients experience residual weakness after 3 years. A small proportion of patients die, and 20 percent of hospitalized patients can have prolonged disability.

¹⁹ *Guillain-Barre Syndrome Among Adolescents Who Received Meningococcal Conjugate Vaccine Factsheet*, November 9, 2005, U.S. Food and Drug Administration, available at <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01238.html>.

²⁰ Morbidity and Mortality Weekly Report, *Guillain-Barre Syndrome Among Recipients of Menactra Meningococcal Conjugate Vaccine – United States*, June-July 2005, October 6, 2005, Department of Health and Human Services Centers for Disease Control and Prevention, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1006a1.htm>.

²¹ *Vaccine Information Florida Vaccine Requirements*, National Network for Immunization Information, available at http://www.immunizationinfo.org/vaccineInfo/disease_stateinfo.cfv; *Immunization and Record Requirements*, available at http://www.doh.state.fl.us/disease_ctrl/immune/school.pdf.

Immunizations required for 7th grade entry:

- Hepatitis B Series
- Second Dose of Measles Vaccine (preferably MMR vaccine)
- Tetanus-Diphtheria Booster

Immunizations required for college/university students:

- MR, M2 (All freshman and new enrollees in public universities)
- Meningococcal (All college/university students who live in dorms, or must sign waiver)

Immunizations required for childcare and/or family day care (up-to-date for age):

- Diphtheria-Tetanus-Pertussis
- Haemophilus influenzae type b
- Measles-Mumps-Rubella
- Polio
- Varicella

All Florida postsecondary educational institutions must provide detailed information concerning the risks associated with meningococcal meningitis and its associated vaccines to every student or to the student's parent if the student is a minor. As noted above, all Florida college and university students who live in campus dormitories are required to be immunized against meningococcal disease or decline the immunization by signing a waiver.²²

III. Effect of Proposed Changes:

Section 1: Amends s. 381.005, F.S., by redesignating present subsection (3) as subsection (4) and adding a new subsection (3) requiring each licensed assisted living facility to implement a program to offer immunizations against influenza viruses and pneumococcal bacteria to all residents age 65 or older in accordance with certain recommendations; requires DOH to annually provide reminder notices to assisted living facilities.

Section 2: Amends s. 1003.22(10), F.S., relating to school-entry health examinations to create a new paragraph (c) which requires district school boards and private school governing authorities to provide every student's parent specified information about meningococcal disease in accordance with DOH recommendations; the bill requires DOH to adopt rules consistent with recommendations of ACIP and requires district school boards and private school governing authorities to determine means and methods for providing information to students' parents.

Section 3: Provides an effective date of July 1, 2006.

²² S. 1006.69, F.S.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Assisted living facilities will incur additional costs to design and implement the program required by the bill.

Private school governing authorities may incur costs related to the provision of information about meningococcal disease to students' parents.

C. Government Sector Impact:

This bill will not have an impact on DOH. The vaccine against meningococcal disease is not required for school attendance. If parents choose to have their children age 11 to 12 years vaccinated, this can be done at the county health departments (CHDs) through a grant from the CDC. Other individuals that present to the CHDs would be required to pay for the vaccine.

This bill also requires public school boards to provide every student's parents with specified information about meningococcal disease. This should have a minimal fiscal effect on the school boards as most already provide information pertaining to immunization schedules.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

Barcode 364544 by Health Care:

Deletes the first section of the bill requiring each licensed assisted living facility to implement a program to offer immunizations against influenza viruses and pneumococcal bacteria to all residents age 65 or older in accordance with certain recommendations (WITH TITLE AMENDMENT)

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
